

Prostate-Specific Antigen Screening: Friend or Foe?

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Prostate cancer (PCA) is expected to be the most frequently diagnosed cancer for men in the United States in 2007, with an estimated 218,890 new cases anticipated for 2007. The National Cancer Institute expects 27,050 deaths from PCA in 2007 (National Cancer Institute [NCI], 2007). Based on published rates during 2000-2004, one out of every six men will be diagnosed with prostate cancer during their lifetime (NCI, 2006a). The prostate-specific antigen (PSA) blood test has become the screening tool of choice for the detection of

Prostate cancer is the most frequently diagnosed cancer among men in the United States. The prostate-specific antigen (PSA) blood test is the most commonly utilized test to detect early prostate malignancy. Elevated PSA levels suggest to providers the possibility that their patients are at a higher statistical risk of harboring asymptomatic, organ-confined prostate cancer. Although PSA testing has become a primary screening method for prostate cancer in the United States, this test has come under scrutiny. PSA screening lacks a high level of specificity due to frequent false-positive results. Additionally, major health organizations differ in their screening recommendations for use of the PSA test. However, the medical community, and more importantly, patients, must understand the benefits and possible detriments of this screening test. Providers should approach each man individually when recommending a PSA test, noting that many risk factors must be considered in a screening protocol for prostate cancer.

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prostate cancer in men, since its approval in 1992 by the Food and Drug Administration (Han, Gann & Catalona, 2004). Prior to the discovery of this blood test, the majority of prostate cancers were identified in an advanced and incurable stage. As low-stage prostate cancer has few signs or symptoms, the discovery of a screening test that could identify localized, and potentially curable disease, has been considered a valuable diagnostic tool. PSA has been reported to be an aide in diagnosing early-stage prostate cancer; however, controversy surrounding this screening test exists.

Several authorities question the utility of the PSA blood test as a screening tool for PCA. For example, normal ranges used for PSA values are somewhat arbitrary. There is poor correlation between the serum PSA values and the actual existence of PCA

in any individual patient, leading to the potential for the over-diagnosing of insignificant prostate tumors. Even though overall mortality from prostate cancer has clearly improved in the "PSA era," it is still unknown whether this change is a result of increased screening, improved treatment, or other factors. There are two major, ongoing, clinical trials looking at whether PSA screening actually influences PCA mortality (NCI, 2006b; Schroder, 2005). In the meantime, there is no clear consensus on how best to use PSA as a screening test, as evidenced by the fact that several national health organizations differ in their recommendations for PCA screening and the use of PSA.

Many prostate cancers are indolent and pose no threat to life, while others are virulent and life threatening. While all prostate cancers will not cause

death, they may cause morbidity (Tanagho & McAninch, 2004). The broad spectrum of this biological activity causes complexity when screening protocols are proposed. The purpose of this article is to review the medical evidence and controversy surrounding PSA screening.

Methodology

Data were obtained from the following sources: Evidence-Based Medicine Reviews, Medline, and CINAHL (1991-2007). Database searches were performed using the terms: prostate-specific antigen, PSA, prostate cancer, prostatectomy, prostatic hyperplasia, prostate cancer screening, and prostate cancer costs. Statistics and research material from government databases were used regarding the prevalence of prostate cancer, the recommendations for screening, and the treatment options.

Prostate-Specific Antigen

PSA is a 27 kilodalton glycoprotein produced by the prostatic epithelium and periurethral glands (Han et al., 2004). It is a serine protease that causes the liquefaction of congealed seminal fluid and is thus a normal product of the prostate gland and normal component of the seminal fluid. Minute amounts of this protein leach into the blood and are detectable quantitatively by a number of chemical assays. Catalona and colleagues (1991) first reported the use of PSA serum levels as a first-line screening tool to detect prostate cancer. These researchers found that a single PSA determination was more accurate than a digital rectal exam (DRE), heretofore, the standard and only method available to detect PCA, and to identify early PCA (Catalona et al., 1991). Evidence followed supporting that a normal serum PSA (sPSA) was defined as less than or equal to 4.0 ng/ml (Catalona, Smith, & Ornstein, 1997). Scientists reported that 35% to 45% of men with PSA

values above this level had a significant prostate cancer (Durkan, Sheikh, Johnson, Hildreth, & Greene, 2002; Han et al., 2004). The sensitivity (a positive test for men with prostate cancer) with a sPSA greater than 4.0 ng/ml was reported as being 67.5% to 80%, while the specificity rate (a negative test for men without disease) was 60% to 70% (Brawer, 1999).

PSA, being a chemical naturally produced in a normal prostate gland, can be excreted into the blood at variable levels, thus causing serum values to vary, even in patients without PCA. Thus, false-positive tests are not uncommon as noted by the relatively low specificity rate. Ascribing the cause of an elevated PSA can be difficult since many factors can cause changes in the serum level. Elevated serum levels of PSA may be indicative of an abnormality with the prostate; however, it is not disease specific (Han et al., 2004). Examples of the etiology of elevated sPSA in the absence of malignancy include benign prostatic hyperplasia, prostatitis, prostatic infarction, physical activity, ejaculation, DRE, other urinary tract infections, urinary retention, prostate surgery, and urethral catheterization.

Consequently, researchers developed additional methods of evaluating the PSA along with other risk factors in the hope of predicting PCA accurately. Refining PSA has been the goal of research in order to decrease the number of false-positive tests and improve both sensitivity and specificity.

The serial PSA value, or PSA velocity, is a measurement that compares the values of PSA over time. A rise of more than 0.75 ng/ml during a 12-month period, utilizing at least three separate data points, is considered to be suspicious for prostate cancer (Carter et al., 1992; Thompson, Ankerst et al., 2005). Carter and colleagues (2006) proposed that PSA velocity may be more accu-

rate in identifying life-threatening disease than static PSA determinations. These researchers believe that PSA velocity may have the greatest value in predicting potentially mortal prostate malignancies at a curable stage, particularly in younger men (Carter et al., 2006).

Benign prostatic hyperplasia (BPH) will also produce PSA. By virtue of age, BPH is very prevalent in men considered at risk for PCA. Therefore, examining the PSA density (the relationship between the prostate volume and serum PSA levels) can reveal information regarding the potential benign or malignant prostate tissue generating the PSA glycoprotein (Tanagho & McAninch, 2004).

Another interesting and poorly understood association is the relationship of PSA found freely circulating in the blood (fPSA) with PSA bound to other serum proteins such as albumin, trypsin, and chymotrypsin. The ratio of free PSA (fPSA) to total PSA (tPSA), which is defined as the amount of both free and bound PSA, has a predictive correlation with the statistical risk of harboring PCA. In men with a tPSA between 4 and 10 ng/ml and a "fPSA/tPSA" ratio greater than 0.25 the PCA risk is 6%; whereas, men with f/t PSA ratios below 10% with similar total PSA values have a PCA risk of 56% (Catalona et al., 1998; Han et al., 2004).

Normal PSA levels appear to change with age. Therefore, the predictive value of elevated PSA in detecting PCA also need to be correlated to age. The "age-adjusted PSA" has thus been suggested for screening (see Table 1).

Catalona and colleagues (1997) discovered that initial PSA levels greater than 2.5 ng/ml increase a man's lifetime risk of developing PCA; therefore, he suggests a baseline PSA be obtained at age 40. Men between ages 40 and 49 years have median PSA values ranging from 0.7

Table 1.
Age-Specific Reference Ranges for Serum PSA

Age Range	Asians	African-Americans	Whites
40-49 years	0-2.0 ng/mL	0-2.0 ng/mL	0-2.5 ng/mL
50-59 years	0-3.0 ng/mL	0-4.0 ng/mL	0-3.5 ng/mL
60-69 years	0-4.0 ng/mL	0-4.5 ng/mL	0-4.5 ng/mL
70-79 years	0-5.0 ng/mL	0-5.5 ng/mL	0.6.5 ng/mL

(Richardson & Oesterling, 1997)

to 1.23 ng/dL (Loeb et al., 2006). Parenthetically, it was reported that a static PSA greater than 2.5 ng/mL in a man less than age 50 years was a strong indicator for prostate cancer risk (Loeb et al., 2006).

Age adjustment also applies to older men. Men over 60 years of age have higher reference ranges (Richardson & Oesterling, 1997). Thus, when considering guidelines to evaluate men at risk for PCA, one should note that older men likely have higher serum PSA values than younger men and that higher PSA levels in older men are expected and may be less significant for predicting significant PCA. Finally, PCA is often indolent, requiring 10 years or more from the time of diagnosis to cause morbidity or mortality. Current scientific opinion indicates that men who have a life expectancy of less than 10 years are unlikely to benefit from PCA screening or even treatment of their disease (Walter, Bertenthal, Lindquist, & Konety, 2006).

Screening Recommendations

The American Urological Association (AUA) and American Cancer Society (ACS) recommend offering a screening PSA along with a DRE for men age 50 and above who are expected to live longer than 10 years. Men at higher risk, such as, African Americans and men with a family history of PCA, should begin testing at age 40 to 45, or 5 years before the age of onset of disease of the affected family member. The DRE

is considered an integral part of the screening protocol and is utilized in conjunction with the PSA, according to the AUA and ACS. The sensitivity of diagnosing tumors is markedly improved with the use of both modalities (Coley, Barry, Fleming, & Mulley, 1997).

The diagnosis of PCA is made by pathologic tissue examination based on prostate biopsy. The issue surrounding PCA screening is the indication for recommending a prostate biopsy. Currently, The AUA recommends prostate biopsy for patients with a total serum PSA value of 4.0 ng/dL or greater, a significant PSA velocity change, or any suspicious DRE abnormality (AUA, 2000). This combination of tests for screening allows providers to detect prostate cancer at earlier stages than historical screening modalities (Bill-Axelson et al., 2005).

An inclusive screening program for PCA should also include several other risk factors such as first or second degree relatives with PCA, ethnic background, and diet. These categories of men should begin screening at age 40 (Moul, 2003). There is evidence that a diet high in animal fat may contribute to a higher possibility of cancer (ACS, 2007).

Decision making with regard to offering patients screening is made even more difficult, as several medical organizations vary widely in their recommendations for PSA screening (see Table 2).

There is not universal support

for mass screening for PCA (Cookson & Smith, 2000). Several studies suggest that PCA screening does not affect disease-specific survival, and that there may be an over-diagnosis of insignificant prostate cancers (Albertsen, Hanley, & Fine, 2005; Schroder, 2005; Walter et al., 2006). Thus, many epidemiologists and health care payers find the current recommendations unacceptable. Screening policy must, therefore, balance financial considerations and scientific rationale (Schroder, 2005). The feasibility of a screening program must meet criteria as an efficacious tool:

- Disease must be prevalent and serious enough to require screening. Prostate cancer meets this requirement.
- Early, pre-symptomatic disease must be detected by the test. PSA and DRE used together would meet this condition.
- Evidence must be present to show that early discovery of the disease will reduce morbidity and/or mortality. This requirement remains unproven and debatable (Cookson & Smith, 2000).

The lead time for PSA screening (the interval of time between laboratory detected disease and clinically detected disease) was estimated at 12.3 years in the European Randomized Study for Screening of Prostate Cancer (Wilson & Crawford, 2004). Lead time may depend upon the patient's age, screening intervals, and treatments used (Schroder, 2005). Since prostate tumors frequently have slow-growing characteristics, screening may lead to over-diagnosis (Kramer, Brown, Prorok, Potosky, & Gohagan, 1993). Early detection of PCA does not necessarily mean that the cancer will cause the patient's death as the patient may die from other causes before the cancer becomes symptomatic (Parker, 2004). Early detection may increase the time that the

Table 2.
Recommendations for Screening

Organization	Published Recommendations for Screening
American Urologic Association	The prostate-specific antigen (PSA) test and the digital rectal examination (DRE) should be offered annually, beginning at age 50, to men who have a life expectancy of at least 10 years. Men at high risk should begin testing at age 45.
American Cancer Society	Annual screening: The American Cancer Society believes that doctors should offer the PSA blood test and DRE (digital rectal exam) yearly, beginning at age 50 to men who do not have any major medical problems and can be expected to live at least 10 more years. Men at high risk should begin testing at age 45. Men at high risk include African Americans and men who have a close relative (father, brother, or son) who had prostate cancer before age 65. Men at even higher risk (because they have several close relatives with prostate cancer at an early age) could begin testing at age 40. Depending on the results of the first tests, they might not need more testing until age 45.
United States Preventative Services Task Force	There is insufficient evidence to support prostate cancer screening.
National Cancer Institute	No published standards or guidelines. The National Cancer Institute posts information: "What is PSA?" "Why is PSA performed?" "For whom is it recommended?" http://www.cancer.gov/cancertopics/factsheet/Detection/PSA
American College of Physicians	There is insufficient evidence to support prostate cancer screening.
American College of Family Physicians	No published standards or guidelines.
Center for Disease Control	Although there is good evidence that PSA screening can detect early-stage prostate cancer, evidence is mixed and inconclusive about whether early detection improves health outcomes. Additionally, prostate cancer screening is associated with important harms, which include anxiety and followup procedures based on test results that sometimes are false positive, as well as the complications that may result from treating prostate cancers that, if left untreated, might not have affected the man's health.
US Department of Veterans Affairs	There is insufficient evidence to support prostate cancer screening.
National Comprehensive Cancer Network	Practice Guidelines in Oncology suggest "talking points" to discuss with patients. The pros and cons of screening are listed within this guideline. Men should make an informed decision about having a PSA screening test.

patient is aware of the disease, without changing the progression or outcome of the disease. Lead-time bias is implied if mortality is not affected by treatment as it appears that screening helps to improve survival (Wilson & Crawford, 2004). PSA screening has been accused of lead-time bias since many of the tumors do not change the time of death. Screening and treatment must be considered together as the cancer that is identified and treated due to screening should lead reduced mortality rates.

There would be less debate about PCA screening if the mor-

bidity from the various treatments were insignificant. It is encouraging that treatment options for localized disease have improved over the years, resulting in decreased morbidity with active surveillance for watchful waiting, improved surgical techniques, and more accurate delivery of radiation therapy. There have been improvements in quality-of-life issues such as incontinence (Jacobsen, Moore, Estey, & Voaklander, 2007). Future studies hope to show continuing improvement in erectile function following surgical treatment. Most important, treatment for localized disease has a very high survival

rate of approximately 99% over a 5-year period. (Thompson, Bermejo, Hernandez, Basler, & Canby-Hagino, 2005). A significant point is the noted reduction in distant metastasis and tumor progression following radical prostatectomy compared to watchful waiting, although overall mortality rates did not change in this research study (Bill-Axelsson et al., 2005)

Epidemiology

There is a genetic component to PCA. For example, men with a first-degree relative with prostate cancer have a two to three times greater risk of developing PCA

compared to men without a familial history of disease (American Society of Clinical Oncology [ASCO], 2006). This inherited trait occurs in about 5% of prostate cancers (ASCO, 2006). Early studies of PCA risk focused on linkage studies that were attentive to families with an extensive history of PCA. These early studies suggested that rare, autosomal dominant genes such as the BRCA1, BRCA2 genes in breast cancer, and the APC gene in colon cancer would lead to the discovery of the PCA gene. Researchers have found at least 10 loci for PCA susceptibility; however, followup studies of these genes fail to consistently validate findings (ASCO, 2006; National Institutes of Health [NIH], 2006; Shaid, 2004). More recently, two independent genome wide association studies identified the 8q24 locus with prostate cancer, as well as colon cancer (Haiman et al., 2007; Yeager et al., 2007). There is currently no genetic test available to determine a man's probability of developing prostate cancer based primarily on his genetic code (ASCO, 2006).

African-American men clearly have a higher incidence and mortality rate due to prostate cancer (NIH, 2006). An African-American man is 1.6 times more likely to be diagnosed with PCA as compared to a white man (Jayadevappa, Chhatre, Weiner, Bloom, & Malkowicz, 2005). African-American men often present with a higher stage of cancer and, as a result, die at a younger age (Jayadevappa et al., 2005). There are many factors that may be causing this racial difference. Genetic factors are being studied, but environmental and social factors are also being considered. According to the U.S. Department of Health and Human Services (USDHHS, 2003), African Americans have a poorer quality health care and have less access to medical treatment. Data suggests that this racial difference may stem

from the fact that fewer African Americans have health insurance and live at a lower socioeconomic level (USDHHS, 2003).

Historically, African-American men have been reluctant to see a physician because of past, abusive, and unethical medical trials, such as the Tuskegee Syphilis Treatment Study (Chan, Haynes, O'Donnell, Bachino, & Vernon, 2003). Fear and embarrassment may accompany the prostate cancer screening since men know that a DRE will be included in that evaluation. Chan and associates (2003) found that African-American men were less receptive to the DRE as they associate the examination with homosexuality. The screening of African-American men should be considered vital due to the impact of the elevated risk of disease in this patient population (Demark-Wahnefried, et al., 1995).

PSA Screening Movement

Use of the PSA blood test has become a routine of practice in the United States. The American Cancer Society and the American Urological Association both recommend PSA and DRE screening for PCA. This has led Medicare to approve payment of one screening PSA test per year. PSA screening is prevalent across the country, as Sirovich, Schwartz, and Woloshin (2003) reported that 75% of men age 50 and older have had a PSA drawn. Of that group of men, 54% stated that they were up to date with the annual test. The momentum for PSA screening has only increased the public demand due to information fed from the medical community, the media, the press, blue ribbon panels, and public figures, such as General Norman Schwarzkopf, Harry Belafonte, and Bob Dole, who speak openly about their experiences with prostate cancer. Recommendations abound that men participate with prostate screening programs. Due to the high prevalence of the disease in the general population, many

men are aware of other men, family, friends, or associates, who have had PCA. These men are likely to request screening evaluations from their providers (Sirovich et al., 2003).

Finally, many practitioners will recommend the test for patients due to the "standard of care" practices in their community. Patients' expectations and the medical liability issue weigh heavily on decision making with regard to screening for PCA (Sirovich et al., 2003). The model of shared decision making is recommended as a way for practitioners to guide patients when considering a PSA screening test. This is a complex process that involves the unbiased sharing of information and relies on the patient's understanding of medical issues (Sheridan, Harris, & Woolf, 2004). This model requires that the practitioner inform the patient of the risks and benefits of having a certain test performed, or not performed. Then together a decision would be made as to the best course of action for the individual patient.

Screening Controversies

So why does controversy exist concerning the use of the PSA blood test as a general screening tool for the early detection of prostate cancer? First, the very researchers who

initially reported its efficacy as a tool for detecting significant PCA at an early stage have recently cast doubt on their original opinions of the value and validity of the test. Second, the standard "normal" range of PSA is arbitrary. Thompson and colleagues (2004) state that there is no safe reference range for the normal value for PSA. Biopsy-detected cancer has been found in 15% to 20% of men who had PSA levels in the "normal" range of 2.5 to 4.0 ng/ml (Catalona et al., 1997; Thompson et al., 2004). That being noted, lowering the acceptable normal PSA values will improve the specificity of

the test; however, the selectivity would be altered as the majority of patients with an elevated PSA values *do not* harbor disease. The false-positive rate for an elevated sPSA is approximately 75%, based on pathologic evaluation of tissue obtained by prostate biopsy (Arcangeli, Ornstein, Keetch, & Andriole, 1997).

There is accumulating evidence that not all PSA-detected PCA is significant. The study by Albertsen and colleagues (2005) collected over 15 years, from the time of diagnosis of clinical stage T1c disease, revealed no increase of cancer progression rates for men treated with watchful waiting or hormone therapy than for men treated with surgery or radiation (Albertsen et al., 2005). These authors suggest that men with low-grade disease often will live a long time after their diagnosis without treatment. Conversely, Johansson, a long time proponent of surveillance only for PCA patients, abruptly altered his recommendations in a landmark article reported in *JAMA* (Johansson et al., 2004). Johansson and colleagues (2004) observed that there are unequivocally subsets of patients, screened for and diagnosed with PCA for whom surveillance is not appropriate. In fact, younger men with life expectancy greater than 10 years and harboring less well differentiated tumors performed much worse in the surveillance group compared to the treated group. Also noted was an increasing morbidity of local and distant complications of untreated PCA as time progressed from the time of diagnosis. Thus, this well-published proponent of watchful waiting only has altered his own course to recommend treatment of high-risk patients.

Harris and Lohr (2002) stated that there is not enough evidence to verify if early detection reduces prostate cancer death. The NCI (2006a) listed several caveats pertaining to the use of PSA as a screening study on their

published fact sheet:

- PSA may detect slow-growing tumors that may never cause harm.
- Most men with an abnormal PSA do not have cancer.
- Cancer may be present in men with normal PSA values.

The United States Preventative Services Task Force (USPSTF) concurs with the National Cancer Institute by stating that screening for PCA has possible harmful effects. False-positive results can lead to unnecessary anxiety and biopsy, and that early detection and treatment for insignificant cancer is needless (Harris & Lohr, 2002). The USPSTF concluded that clinicians should not order screening without discussing all of the possible risks that accompany the PSA test. The Centers for Disease Control and Prevention (CDC, 2006) recommends balanced information be provided to men regarding the pros and cons of screening. Their decision guide states that the medical experts are unclear if the benefits of screening outweigh the known side effects of treatment (CDC, 2006). Thus, providers are left in a quagmire (see Case Study).

Financial Considerations

Treating prostate cancer has direct and indirect costs. The direct health care costs include physician services, hospitalization, medications, and home health care. Indirect costs include loss of productivity from work, time spent dealing with the illness, transportation, household help, education, medical supplies, and long-term care of the disease and complications of treating the disease (Max et al., 2002). Due to the prevalence of the disease and the aging population of men, the annual cost of treating PCA will grow to several billion dollars per year (Jayadevappa et al., 2005). The treatment of PCA was found to

cost approximately \$35,000 per case when all treatment options including all stages of cancer were calculated for the year 2000 (Ruchlin & Pellissier, 2001). The costs of PCA will rise as men live longer and screening continues. Medicare will be required to cover the large amount of these costs for the elderly. The cost effectiveness of screening has been difficult to calculate due to the uncertainties about the benefits of the PSA test (Harris & Lohr, 2002).

Psychological Effects

The psychological effect of PCA screening also deserves consideration. Pain, suffering, and psychological distress should be included as associated costs of the treatment (Max et al., 2002). Men may experience high levels of anxiety while awaiting results from testing (NCI, 2006c). This anxiety may enter the day-to-day affairs and affect work or personal relationships. The impact of a cancer diagnosis is life changing. The impact of false-positive screening tests is also significant. "Anxiety associated with cancer may increase feelings of pain, interfere with one's ability to sleep, cause nausea and vomiting, and interfere with the patient's quality of life" (Dana Farber Cancer Institute, 2006, para. 1). Following the receipt of a diagnosis of prostate cancer, a patient will enter into a category from which he cannot escape. From the time the diagnosis is given to the patient, he has cancer, indolent or not, and he is filled with profound fear and dread. This very point makes the option of watchful waiting difficult for many men as they may not be comfortable "not treating" their cancer. Additionally, pressure to act is often encouraged by well-intentioned, but under-informed family members and friends who argue to actively "fight the cancer." Men with prostate cancer also often wish to begin aggressive treatment as

Table 3.
Issues that Favor and Discourage PSA Screening

Issues that Favor PSA Screening	Issues Against PSA Screening
PSA is a simple blood test.	The aging population (with age-related higher PSA values) will increase the need for screening.
Prostate cancer is the second cause of death for men in the United States.	No randomized trials have proven that screening will reduce prostate cancer mortality.
One in six men will have prostate cancer during his lifetime.	The majority of men screened for prostate cancer will not die from prostate cancer even without screening.
Serial changes in the annual PSA test can be used to calculate the PSA velocity that can identify more aggressive disease.	Lowering the PSA threshold (<4.0 ng/mL) as proposed by recent studies will increase the number of recommended prostate biopsies.
Symptomatic prostate cancer is usually advanced and metastatic.	Detected prostate cancer may not be clinically significant.
Screening is able to detect localized, usually treatable disease.	Aggressive, incurable prostate cancer may be found. Screening and treatment may not change the course of these tumors.
Treatments for prostate cancer have improved which have improved quality of life issues especially incontinence and erectile dysfunction.	Treatment for prostate cancer has associated side effects and alterations in quality of life.
Steady decline in mortality rates: early detection vs. improved treatment effects unknown at this time.	Elderly men (>75 years) screened and diagnosed with prostate cancer may not live long enough for benefit from treatment.

(Thompson, Bermejo et al., 2005)

soon as possible to avoid the associated morbidity and possible mortality caused by prostate cancer without full knowledge of the disease's potential course.

Conclusion

The current inconsistencies with regard to the recommendations for using the PSA blood test as a screening tool for prostate cancer screening leaves practitioners with many questions. Evidence-based outcomes data are often interpreted differently by different authorities. Ongoing debate will continue in editorials, journal articles, and, unfortunately, by the tort bar. Table 3 summarizes the multiple issues that surround this debate. There does not appear to be one right or wrong answer for the query: "PSA Screening: Friend or Foe?"

Thompson and colleagues (2006) developed a risk calculator that computes factors to

determine if prostate biopsy should be recommended. A patient or practitioner enters the required values and receives a probability number regarding suspicion for cancer. The disclaimer page emphasizes the parameters that were set when the calculator was developed. This is a new method of prediction and further data will need to be collected to establish its reliability (Thompson et al., 2006). The prostate risk calculator is available online at <http://www.compass.fhcrc.org/edrnci/bin/calculator/main.asp>. It should be noted that both the PSA value and DRE determination are variables that this calculator requires for evaluation. Men will need to continue their annual blood test and visit to the doctor's office for examination to use this calculation.

The future for prostate cancer screening, diagnosis, and

treatment may well be guided by two large ongoing evidence-based trials. The National Cancer Institute is conducting a study to determine whether certain cancer screening tests will reduce death from cancer (NCI, 2006b). The European Randomized Study of Screening for Prostate Cancer is a large trial in seven countries in which the investigators are following 215,000 men. Both of these randomized trials will evaluate the screening of prostate cancer, quality of life factors, cost effectiveness, and specific mortality associated with prostate cancer (Han et al., 2004).

Men should be counseled about the risks and benefits of screening. They should be told that the PSA test has a margin of error that can cause undue worry and subsequent treatment. Providers should assess all factors for each individual when

Case Study

Medico-Legal Considerations

The shared decision-making model is well documented. However, in the current medico-legal climate present in the United States today, even this well-respected medical practice model may not protect the practitioner from medical malpractice liability, as illustrated by an index case presented by Merenstein (2004). This case illustrates the risks of shared decision making. The practitioner, in this article, describes his malpractice law suit following a well-documented office visit with a patient. The physician discussed the risks and benefits of screening with the patient. That patient declined the PSA test after consulting with the physician. However, the patient had the PSA test drawn later and was eventually diagnosed with advanced prostate cancer. During the trial, the patient's attorney argued that the patient should not have been given the choice of screening at the original appointment and that the physician should have just ordered the test. The jury found in favor of the plaintiff and the residency program was found liable for \$1 million (Merenstein, 2004). Malpractice losses may influence clinical practice and recommendations for prostate cancer screening in the future.

screening for prostate cancer. The man's age, race, family history, medications, life expectancy, and prostate size must all be evaluated. Family history should include a three-generation pedigree to assess the individual's risk (Wattendorf & Hadley, 2005). There is evidence to support an educated use of the PSA test and the available variables of the test. The bottom line is that PSA will continue to be used until there is a better biomarker to diagnose prostate cancer and differentiate between indolent and aggressive tumors. ■

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